

# SPL Vendor Training Session

Lonnie Smith  
Policy Analyst  
Structured Product Labeling Team  
FDA Data Standards Council



# SPL Implementation Guide/Validation Procedures

- Combination of SPL IG and validation procedures documents
- Relevant information will be retained in new version
- Eliminate need to maintain two documents with similar code snippets, etc...

# Country Code - Coding

<addr>

...

<country code="USA" codeSystem="1.0.3166.1.2.3">United States of  
America</country>

</addr>

Or

<addr>

...

<country code="USA" codeSystem="1.0.3166.1.2.3">USA/country>

</addr>

# Translation Element

- Proposed for removal from package coding
- Does not add value to data in SPL file

# Business-to-Product Data Relationship

- Implementation timeline currently being discussed
- Time needed for updating SPL software will be considered
- SPL stylesheet has been updated to render this data relationship
- If your software has already been updated to include this type of relationship, please let us know

# SPL-to-PDF Stylesheet Files

- FDA will no longer maintain the SPL-to-PDF stylesheet files for external use
- New format for SPL conversion format will be utilized but not provided to public

# SPL Stylesheet Testing

- Considering making updated versions of SPL stylesheet available a few days prior to official posting
- Comment period – 3 or 4 days

# Zip Files Transmitted to FDA Centers

- CDER has reported an increase in the amount of zip files erroneously transmitted via the CDER Gateway portal
- Zip files should not be transmitted via the CDER or OC Gateway portals



# SPL R4 Format

- Versions of SPL files in SPL R3 format should be converted to SPL R4 format ASAP

# FDA Online Label Repository

- FDA Online Label Repository launched
- Only contains SPL R4 submissions
- [Labels.fda.gov](http://Labels.fda.gov)

# SPL Vendor Challenge

- SPL vendor challenge being proposed for next major SPL meeting (DIA or a face-to-face training session)
- Similar to SPL vendor challenge held in June 2004
- Details to be published soon

# Home Use Medical Device SPL Pilot

- Pilot announced via Federal Register notice
- Commencement of pilot – October 2010
- SPL software vendors interested in testing the coding of files created utilizing the home use medical device SPL Xforms – contact SPL team at [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov)

# Terminology

- UNII requests should be submitted well in advance of date for submission of file containing UNIIIs
- Downloadable terminology XML
  - Current – Several XML files each with a specific type of terminology
  - For consideration – One XML file with all SPL terminology (with the exception of UNIIIs)

# Removing SPL Files From DailyMed

- Proper method - submission of an SPL R4 document with a marketing status of “completed” and marketing end dates for all products described in file.

# Follow SPL IG/VP

- Please use the code snippets in the SPL IG/VP documents as a guide.
- FDA and downstream users expect that the coding in the SPL files will match the description in the SPL IG/VP document.

# Image Files

- Text in image files should be legible
- Hospital staff and others depend on legible text and will report issues to FDA
- Size of each image file should be well under the 1 mb limit. Under 500 kb should be sufficient



Questions